

THE UNIVERSITY OF NORTH CAROLINA AT ASHEVILLE
FACULTY SENATE

Senate Document Number 8913S

Date of Senate Approval 05/02/13

Statement of Faculty Senate Action:

FWDC 10 : **Institutional Review Board Policy Revisions**
(Replacing [Section 4.3.6.2](#) of Faculty Handbook
Replacing [Section 10.4.20](#) of Faculty Handbook
Concerns [SD0393F](#) and [SD3110S](#))

Effective date: Fall 2013

Summary: This document revises the faculty handbook section on the Institutional Review Board. These revisions:

- 1) Update the handbook to bring it in accord with current IRB policies,
- 2) Refer faculty members to the IRB website for specific procedures and documents,
- 3) Revise the membership to align with federal regulations, and
- 4) Provide links to the federal regulations with guide the operation of the IRB.

Rationale: The Institutional Review Board (IRB) has changed its composition and practice in response to revisions in federal regulations and faculty concerns about procedures. Compliance with the Code of Federal Regulations requires IRB approval for any research on human subjects, and is necessary in order to receive any federal funding. This update brings the faculty handbook into agreement with the changes IRB has implemented.

- 1) Replace existing [Section 4.3.6.2](#) with:

4.3.6.2 Institutional Review Board Policy

4.3.6.2.1 Purpose

The UNC Asheville Institutional Review Board (IRB) is charged by the University with reviewing all University activities involving human research subjects, according to the Department of Health and Human Service's Code of Federal Regulations (CFR) for the Protection of Human Subjects ([45 CFR 46](#)), in order to safeguard the welfare and rights of research participants, including research related to class assignments. The UNC Asheville policy on human subjects applies to all faculty, student, and staff research involving human subjects, regardless of funding source. The UNC Asheville IRB reviews

behavioral research protocols; investigators wishing to conduct invasive biomedical research activities should seek approval from an external IRB certified for such review.

4.3.6.2.2 Policies and Procedures

IRB procedures and policy will be updated as necessary in order to remain compliant with 45 CFR 46, and any applicable state or local laws. UNC Asheville IRB policies as well as links to 45 CFR 46 are available at <http://irb.unca.edu>. Faculty members are encouraged to consult this site for updated procedures and documents.

These regulations apply to all University faculty, staff, and students.

Policies on Research Activities

- Except as provided under Exempt Activities ([45 CFR 46.101b](#)), all research activities involving human subjects conducted by UNC Asheville faculty, students, and staff must receive IRB Review before such activities begin. Student projects involving human subjects must be reviewed and approved by the IRB before research activities begin. This includes course-related work.
- The “IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy” (CFR 46.109). Officials of the institution may disapprove research approved by the IRB, but those officials may not approve any research that has not been approved by an IRB. (CFR 46.112).
- The IRB may suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects (CFR 46.113).
- IRB approval is limited to one calendar year (CFR 46.109e), after which continuing review should be sought.
- No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (46.116)
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards may be required to protect the rights and welfare of these subjects (46.111b). Additional regulations may be required for pregnant women and fetuses (46.204), neonates (46.205), children (46.401), and prisoners (46.301).

4.3.6.2.3 Membership

Membership of the IRB conforms to federal guidelines (45 CFR 46.107).

- 6 voting members and 3 alternates, approved by the Provost, in consultation with existing IRB members and FWDC. Faculty members serve staggered three-year terms which may be renewed, while the community representative serves a one-year term which may be renewed.
 - Two faculty members who have expertise in research involving human subjects from a behavioral or biomedical research discipline (e.g., Psychology, Management);
 - At least one faculty member who has expertise in research using the scientific method but not primarily involving human subjects (e.g., Environmental Science, Chemistry) and one or two faculty members from any discipline to bring total voting faculty membership up to five;
 - One member unaffiliated with the university who has expertise in scientific study which may or may not involve human subjects (Community Representative);
 - One alternate from each of the above categories
- Representative from the Office of Sponsored Scholarship and Programs, ex officio and non-voting.
- Liaison from Academic Affairs, ex officio and non-voting, as needed, to facilitate the work of the IRB. The Academic Affairs liaison should not participate in IRB deliberations

In appointing the members of the IRB, attention should be paid to gender, racial, and professional diversity.

Committee members are requested to serve a minimum of one full term as specified above, and must maintain IRB Member CITI Training Certification.

The Chair of the IRB must be a tenured member of the faculty. It is best for the Chair to have served two years as a Committee member prior to assuming the role of Chair, and to serve as Chair for more than one year. At the completion of his or her term, outgoing Chairs are requested to attend IRB meetings for one year after their term, either as a formal member of the committee or as an ex officio non-voting member, to serve as a mentor for the new Chair and to promote consistency and continuity.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals do not have a vote.

No IRB member may participate in an initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB. The Chair determines whether a conflict of interest exists.

A quorum shall be at least four of the six members of the IRB, one of whom must have primary concerns in research not involving human subjects.

Recommendations and reports to: Provost

2) Replace existing [Section 10.4.20](#) with:

10.4.20 Institutional Review Board (SD0393F) (SD3110S)

Purpose

The UNC Asheville Institutional Review Board (IRB) is charged by the University with reviewing all University activities involving human research subjects, according to the Department of Health and Human Service's Code of Federal Regulations (CFR) for the Protection of Human Subjects (45 CFR 46), in order to safeguard the welfare and rights of research participants. The UNC Asheville policy on human subjects applies to all faculty, student, and staff research involving human subjects, regardless of funding source. The UNC Asheville IRB reviews behavioral research protocols; investigators wishing to conduct invasive biomedical research activities should seek approval from an external IRB certified for such review.

Membership

Membership of the IRB conforms to federal guidelines (45 CFR 46.107).

- 6 voting members and 3 alternates, approved by the Provost, in consultation with existing IRB members and FWDC. Faculty members serve staggered three-year terms which may be renewed, while the community representative serves a one-year term which may be renewed.
 - Two faculty members who have expertise in research involving human subjects from a behavioral or biomedical research discipline (e.g., Psychology, Management)
 - At least one faculty member who has expertise in research using the scientific method but not primarily involving human subjects (e.g., Environmental Science, Chemistry) and one or two faculty member from any discipline to bring total voting faculty membership up to five
 - One member unaffiliated with the university who has expertise in scientific study which may or may not involve human subjects (Community Representative)
 - One alternate from each of the above categories

In appointing the members of the IRB, attention should be paid to gender, racial, and professional diversity.

Committee members are requested to serve a minimum of one full term, and must maintain IRB Member CITI Training Certification.

The Chair of the IRB must be a tenured member of the faculty. It is best for the Chair to have served two years as a Committee member prior to assuming the role of Chair, and to serve as Chair for more than one year. At the completion of his or her term, outgoing Chairs are requested to attend IRB meetings for one year after their term, either as a formal member of the committee or as an ex officio non-voting member, to serve as a mentor for the new Chair and to promote consistency and continuity.

Procedures

IRB procedures and policy will be updated as necessary in order to remain compliant with 45 CFR 46, and any applicable state or local laws. UNC Asheville IRB policies as well as links to 45 CFR 46 are available at <http://irb.unca.edu>. Faculty members are encouraged to consult this site for updated procedures and documents.

Recommendations and reports to: the Provost